Teacher Companion for *Deliberative Scenario: Return of Genetic Research Results*

This teacher companion provides instructors with step-by-step instructions for facilitating deliberation. The deliberative scenario, "Return of Genetic Research Results," is particularly well suited for science or government classes in high school and college, and can be used in a variety of other settings.

Phase 1: Before the Deliberation

Provide Background and Context

Provide students with "Deliberative Scenario: Return of Genetic Research Results" and with "Guide to Classroom Deliberation for Students and Teachers." Both are available on bioethics.gov in the *Education* section. If desired, assign additional readings on deliberation from the *Additional Resources* section in "Guide to Classroom Deliberation for Students and Teachers." Ask students to think about the differences between deliberation and debate or discussion, and the goals and method of deliberation.

Clearly state the goal of the deliberation: to develop a consensus on a practical policy for the return of genetic research results to potentially thousands of participants in a study.

Provide all students with the following readings (available online) to learn about incidental findings and interpretation of genetic information.

- Karow, J. (2016, March 4). Clinicians, Patients Discuss Best Ways to Return Complex Genetic Test Results at FDA Workshop. *GenomeWeb*. Retrieved August 1, 2016 from https://www.genomeweb.com/molecular-diagnostics/clinicians-patients-discuss-best-ways-return-complex-genetic-test-results-fda.
- Presidential Commission for the Study of Bioethical Issues (PCSBI). (2013, December). Anticipate and Communicate: Ethical Management of Incidental and Secondary Findings in the Clinical, Research, and Direct-to-Consumer Contexts. Washington, DC: PCSBI, pp. 1-20. Available at: http://bioethics.gov/sites/default/files/FINALAnticipateCommunicate_PCSBI_0.pdf.

Assign Roles

Option 1: Assign each student a role from among the following stakeholders who might serve on the special purpose committee: institutional review board members, researchers, research participants, lawyers, and study administrators.

Option 2: Ask students to generate a list of stakeholders who would serve on the special purpose committee and assign roles from that list, for example: participants' family members, other similar research studies, clinical geneticists, and others. The list should include participants with a wide variety of perspectives on the matter.

Note: You can also assign multiple students to the same role, as even people in the same role can have different perspectives. These readings provide additional perspective for each role.

Assign Role Based Readings

Based on a student's specified role, assign role specific readings from the additional reading section at the end of this document.

Phase 2: During the Deliberation

Questions to Guide and Focus Deliberation

Remind students of the goal of this exercise: To practice democratic deliberation by considering many different perspectives, providing reasons for their arguments, listening respectfully to opposing viewpoints, and finding a way forward. Instruct students to begin the deliberation by introducing themselves and stating which role they will play.

During the deliberation, ensure that the following questions have received sufficient attention. If a question has not been answered, pose the question to the group.

- If we decide to return genetic results to participants, how can we manage anxiety and ensure appropriate follow-up care? (Empirical question: provides factual evidence)
- How should we return results, if any? In person? By telephone? By mail? By notifying their primary care clinician? Another way? What impact will the method chosen have on the research process and budget? (Empirical question: provides factual evidence)
- What effects might this have on future research recruitment? (Empirical question: provides factual evidence)
- If we decide to return *some* genetic results but not others, what should be our criteria for deciding? (Normative question: provides answer to question of what we *should* do)
- What other values might be at stake? (Normative question: provides answer to question of what we *should* do)
- In what ways should the consent process be changed and why? (Normative question: provides answer to question of what we *should* do)
- If we decide genetic results should be returned, should participants have an opportunity to opt out of receiving that information? Why or why not? (Normative question: provides answer to question of what we *should* do)
- What are the legal considerations at stake? (Empirical question: provides factual evidence)
- How might we balance individual interests and societal interests in research? (Normative question: provides answer to question of what we *should* do)

Strategies to Improve the Deliberative Process

If some students are quiet or refrain from contributing, ask the class: Are there any views that have been left out? Whose views might those be?

If there is a swift and seemingly straightforward answer or a premature dominant view developing that could crowd out other views, ask the class: What are some other perspectives that we have not heard or considered yet?

Strategies to Improve Content

If students come up with recommendations without justification, ask the class: How does justice relate to research? Are the recommendations compromising the research enterprise?

Scenario Shift

If the students reach consensus on recommendations with time leftover, you might introduce a shift in the scenario. Pick one or more of the following scenario shifts and ask students to discuss how this new information changes things.

- A new genetic mutation has just been discovered that indicates a 100% chance that the individual will develop a certain disease that can be easily treated. Does this new information alter your policy? If so, how will you update it?
- After you start returning some genetic results, participants start receiving calls from their insurers and employers, asking them to disclose their results. Does your policy recommendation speak to this issue? How will you guide participants to handle these inquiries?

Developing a Policy Recommendation

Ask the students to develop recommendations that reflect the consensus-driven process of deliberation. The recommendations should include mutually acceptable reasons for a policy choice.

Phase 3: After the Deliberation

Presenting the Policy Recommendation

Instruct students to write a half-page press brief for the local newspaper stating their recommendations and the justificatinos for them. Alternatively, ask students to present this information orally.

Assessment and Reflection

Ask the class to reflect on the process and outcome of the deliberation using the following questions.

- Do the recommendations provide reasons for a policy choice?

- Are all of the deliberators satisfied with the outcome? If not, was a dissenting statement included?
- Does this policy recommendation seem more legitimate than one decided by majority vote? By elected representatives? Why or why not?
- What are the strengths of deliberative decision making? What are the weaknesses?
- Is the set of recommendations contingent upon new facts or values coming to light? When would a new deliberation be needed?

Additional Role-based Readings

If the role assigned is an *institutional review board member*, assign the following reading:

- Fabsitz, R.R., et al. (2010). Ethical and Practical Guidelines for Reporting Genetic Research Results to Study Participants. *Circulation: Cardiovascular Genetics*, 3, 574 580, Available at: http://circgenetics.ahajournals.org/content/3/6/574.full. (Working Group Recommendations)

If the role assigned is a *researcher*, assign the following reading:

- Yu, J. et al. (2014). Attitudes of Genetics Professionals Toward the Return of Incidental Results from Exome and Whole-Genome Sequencing. *American Journal of Human Genetics*, 95(1), 77-84 Retrieved August 1, 2016 from http://www.sciencedirect.com/science/article/pii/S0002929714002663#.

If the role assigned is a *research participant*, assign the following reading:

- Hartz, S.M. et al. (2014, August). Return of individual genetic results in a high-risk sample: Enthusiasm and positive behavioral change. *Genetics in Medicine*, 17(5), 1-6. Retrieved April 19, 2016 from http://www.the-scientist.com/?articles.view/articleNo/44369/title/Toward-Protecting-Participants--Privacy/.

If the role assigned is a *lawyer*, assign the following reading:

- Barnes, M., et al. (2015, July 15). The CLIA/HIPAA Conundrum of Returning Test Results to Research Participants. *Bloomberg BNA: Medical Research Law and Policy Report*. Retrieved August 1, 2016 from https://www.ropesgray.com/~/media/Files/articles/2015/July/2015-07-15-Bloomberg-BNA.ashx. (Introduction)

Relevant National Educational Standards

Standards	Category	Sub-Category	Grade levels & bullets/skills	Page(s)
Next Generation Science Standards	Science and Engineering Practices in the NGSS (Appendix F)[1]	Practice 7	**Grades 9-12:** bullets 1, 6	13-14
		Practice 8	**Grades 9-12:** bullets 3-5	15
	Science, Technology, Society, and the Environment (Appendix J)[2]	Core Idea 2	**Grades 9-12:** bullets 3, 4	3-4
Common Core[3]	English Language Arts	Reading Standards for Informational Text	**Grades 9-10:** Skills 1-8	40
			Grades 11-12: Skills 1-7	
		Speaking and Listening	**Grades 9-10:** Skills 1-4, 6	50
			Grades 11-12: Skills 1-4, 6	
	Literacy in History/Social Studies, Science, and Technical Subjects	Reading Standards for Literacy in History/Social Studies	**Grades 9-10:** Skills 1, 2, 4-6, 8	61
			Grades 11-12: Skills 1, 2, 4-6, 8	
		Reading Standards for Literacy in Science and Technical Subjects	**Grades 9-10:** Skills 1, 2, 4, 5, 8, 9	62
			Grades 11-12: Skills 1, 2, 4, 5, 8, 9	

[1] Next Generation Science Standards. (2013). APPENDIX F – Science and Engineering Practices in the NGSS. Retrieved April 19, 2016 from http://www.nextgenscience.org/sites/default/files/Appendix%20F%20%20Science%20and%20Engineering%20Practices%20in%20the%20NGSS%20-%20FINAL%20060513.pdf.
[2] Next Generation Science Standards. (2013). APPENDIX J – Science, Technology, Society and the Environment. Retrieved April 19, 2016 from http://www.nextgenscience.org/sites/default/files/APPENDIX%20J_0.pdf.
[3] Common Core State Standards Initiative. (2010). Common Core State Standards for English Language Arts & Literacy in History/Social Studies, Science, and Technical Subjects. Retrieved April 19, 2016 from http://www.corestandards.org/wp-content/uploads/ELA_Standards1.pdf.